

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



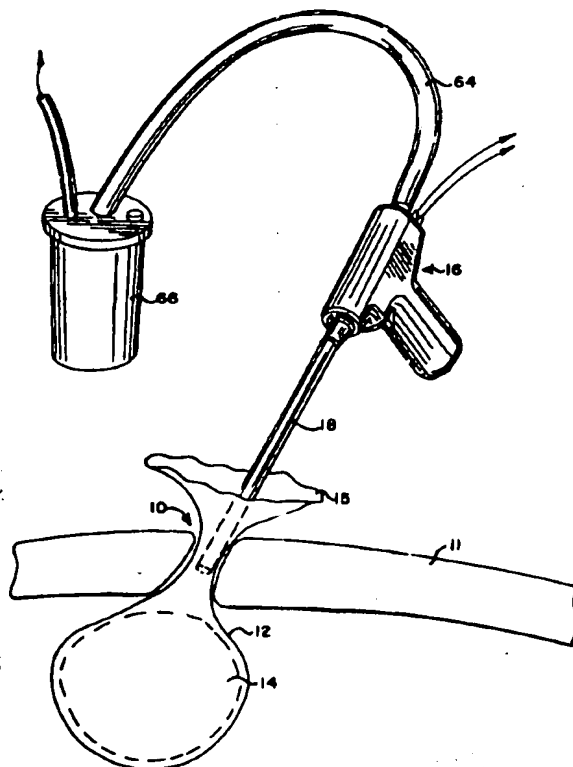
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 17/20, 17/36, A61M 5/32</b>		<b>A1</b>	(11) International Publication Number: <b>WO 96/24296</b>
			(43) International Publication Date: <b>15 August 1996 (15.08.96)</b>
(21) International Application Number: <b>PCT/US96/01547</b>			(81) Designated States: CA, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: <b>6 February 1996 (06.02.96)</b>			
(30) Priority Data: <b>08/386,970</b> <b>10 February 1995 (10.02.95)</b> <b>US</b>			
(71) Applicant: <b>ENABLE MEDICAL CORPORATION (US/US);</b> <b>6345 Centre Park Drive, West Chester, OH 45069-3863 (US).</b>			
(72) Inventor: <b>HOOVEN, Michael, D.; 7778 Bennington Drive,</b> <b>Cincinnati, OH 45241 (US).</b>			
(74) Agent: <b>McFARRON, Gary, W.; Cook, Egan, McFarron &amp;</b> <b>Manzo, Ltd., Suite 4100, 135 South LaSalle Street, Chicago,</b> <b>IL 60603 (US).</b>			<b>Published</b> <i>With international search report.</i>

(54) Title: **APPARATUS AND METHOD FOR MORSELATING AND REMOVING TISSUE FROM A PATIENT**

(57) Abstract

This invention is a method for morselating and removing the morselated tissue (14) through a small incision (10) comprising in general inserting a tissue container (12) into the body cavity of a patient through an incision (10), placing resected tissue (14) in the vessel (12), inserting a morselator (16) having a rotatable electrode thereon through the incision (10) and into the vessel (12), morselating the tissue and removing the tissue from the containment vessel (12) and the body. An apparatus (16) for morselating and removing tissue through a small incision (10) within the body cavity of a patient is also disclosed and may comprise a tissue container (12) having an inner chamber for containing resected tissue (14), and a morselator (16) having a proximal end (21) and a distal end (17) carrying an electrode (36) wherein the distal end (17) is insertable into the body cavity and containment vessel (12) for morselating resected tissue (14).



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

**APPARATUS AND METHOD FOR  
MORSELATED AND REMOVING TISSUE FROM A PATIENT**

5       The present invention relates generally to apparatus and methods for removing tissue from the body of a human patient. More particularly, the present invention concerns novel apparatus and methods for morselating and removing body tissue through a relatively small incision in the patient.

10       **BACKGROUND OF THE INVENTION**

      So-called minimally invasive surgery has become increasingly popular in a variety of surgical procedures. Minimally invasive surgery typically involves introducing surgical devices into a patient through small access  
15       incisions, in contrast to obtaining full and open access to the surgical site through large incisions.

      Briefly, minimally invasive surgery is typically carried out through one or more relatively small incisions, which are usually between approximately ½ and  
20       1½ inches in length, and through which an entry tube or trocar is placed. Optical and medical instruments are inserted through the trocar(s) to allow the physician to view the surgical area and to target the organ or tissue that is the subject of the surgery, and then to carry out  
25       the desired surgical procedure. Because of the relatively small diameter of the trocar(s), however, withdrawal of the target tissue therethrough can be difficult, particularly if the tissue is dense or muscular, such as a kidney, uterus or uterine myoma.

30       One previously accepted technique for removing such tissue required manually cutting the tissue into smaller pieces within the body cavity, which pieces were then

removed through the trocar by graspers. This procedure, however, in addition to being very tedious and time consuming, also suffers from a number of other possible drawbacks, including possible excessive bleeding, possible  
5 accidental cutting of other tissue and possible contamination of the abdominal cavity with target tissue.

A morselation device is described in U.S. Patent No. 5,290,303. That device uses an inner rotating tube and an outer stationary sheath, the inner tube extends beyond the  
10 sheath and has a tapered end for severing tissue. A further outer tube or shield may also be used over the sheath. This device may be used with a tissue bag, such as shown in U.S. Patent No. 5,037,379. The tissue to be morselated may be placed in the bag and the device  
15 inserted into the bag to carry out the morselation within the pouch.

One of the concerns with the device shown in the '303 patent is possible puncture of the pouch by the rotating tube, with accompanying potential contamination of the  
20 anatomical space, as well the time consuming insertion and placement of a new pouch within the body cavity. Although the bag disclosed in the '379 patent has two layers, including a puncture resistant inner layer, the above-mentioned concern is still present. In addition, the  
25 multi-layer construction with a higher strength inner container may make folding and insertion of the pouch into the abdominal cavity more cumbersome.

More recently, in U.S. Patent No. 5,304,124, an apparatus and method were disclosed for removing a uterine  
30 myoma. In that method, a tube is inserted through the trocar and into the myoma. A wire loop, which may energized by radio frequency energy, is located at the distal end of the tube to cauterize the tissue as the tube is inserted into the myoma, resulting in a core of tissue  
35 being located within the tube. A separate morselator is then inserted into the tube to cut up the tissue (such as

by rotary blades, laser, or a rotary whip), and the morselated tissue is then evacuated. Although such a procedure may be an advance over a purely manual procedure, this procedure is still relatively complicated, requiring separate steps and apparatus to core and to morselate the tissue.

In addition, the procedure described in the '124 patent, when utilized with radio frequency ("RF") energy, uses a separate grounding or return electrode or antenna in contact with the skin of the patient, for example, that the patient lies on. As is well known in the art, such an application of RF energy has certain shortcomings. It requires the energy to travel between the electrodes, a relatively long distance through the body, with possible adverse effect on other body tissue. It also may result in accidental injury to non-target tissue, for example, if the active electrode is inadvertently brought into contact with non-target tissue. Also, this patent discloses a relatively complex mechanism to sever the tissue core from the myoma.

Accordingly, it is a general object of the present invention to provide apparatus and methods for removing target tissue through a trocar, which apparatus and method are more simplified and/or easier to use than the apparatus and method described above, and reduces the risk of accidental injury to non-target tissue.

#### GENERAL SUMMARY OF THE INVENTION

As set forth in the appended claims, the present invention is generally embodied in apparatus and methods for morselating and/or removing target tissue from the body cavity of a patient, such as through the relatively small incision(s) that are typically used in minimally invasive surgical procedures.

More particularly, the present invention is generally embodied in a morselator, a tissue container for containing resected tissue to be morselated, and their

methods of use. In general, the morselator of the present invention may comprise an elongated shaft having an inner tube and an outer tube extending between proximal and distal end portions. At least one of the tubes is rotatable and an electrode surface is carried by the rotatable tube(s) in proximity to the distal end thereof.

The foregoing apparatus may be used for removing tissue from within a body cavity of a patient by inserting the distal end through an incision in the patient, energizing and rotating the electrode and advancing the electrode into the resected tissue in order to morselate it. The morselated tissue is then removed through the lumen of the inner tube.

Preferably a second electrode of opposite polarity is used with the first mentioned electrode, with one of the terminals being a RF energy active electrode and the other being a RF energy return electrode, to morselate tissue therebetween. The additional electrode may be located, in one embodiment, at the distal end of the shaft or, when the morselator is used to morselate tissue within a resected tissue container, the additional electrode may be defined within the container, such as by a conductive inner surface of the container or by having the additional electrode otherwise disposed within the container.

In accordance with further aspects of the present invention, the combination of a resected tissue container and a morselator may be provided for morselating resected tissue within the body cavity of a patient. In such a combination, the tissue container is insertable through an incision into a body cavity of a patient. The container defines an interior chamber for containing the resected tissue. The morselator has a proximal end portion and a distal end portion. One electrode is carried on the distal end portion and is operable to assist in the morselation upon insertion through an incision and into the resected tissue container. A second electrode of

opposite polarity also is disposed in the container. In this combination, the resected tissue container contains the resected tissue and helps protect surrounding tissue from inadvertent or undesirable contact with the electrodes or RF energy associated therewith.

In accordance with another aspect of the present invention, a tissue container is provided for containing resected tissue during morselation. The tissue container is comprised of a flexible wall which defines an inner chamber adapted to be received within a body cavity of a patient. The wall comprises a non-conductive outer surface and a conductive inner surface, which inner surface also may serve as an electrode of opposite polarity when only one type of electrode (e.g., active or return) is carried on the morselator.

The above is only a summary of the present invention in certain of its more general aspects. Accordingly, for a more complete understanding of these and other features and advantages of the present invention, reference should be made to the following detailed description.

those modifications, variations and additions that would be readily apparent to one of ordinary skill upon reading this description. Accordingly, for ascertaining the scope of the present invention, reference must be made to the  
5 appended claims.

**What Is Claimed Is:**

1. Apparatus for morselating tissue within a body cavity of a patient comprising:

5 an elongated shaft comprising an outer tube, an inner tube disposed within said outer tube, a proximal end portion, and a distal end portion, said inner and outer tubes being open at their distal ends;

at least one of said inner and outer tubes being rotatable; and

10 at least one electrode surface carried by a rotatable one of said tubes in proximity to the distal end of said tube and being rotatable therewith.

2. The apparatus of Claim 1 further comprising an additional electrode surface carried by said elongated shaft at said distal end portion wherein said one and additional electrode surfaces define electrodes of  
5 opposite polarity for transmission of energy and morselation of tissue therebetween.

3. The apparatus of Claim 2 wherein said one and said additional electrode surfaces are carried on said inner tube.

4. The apparatus of Claim 2 wherein said additional electrode surface is carried on said outer tube.

5. The apparatus of Claim 1 further comprising an electrical conductor extending between said at least one electrode surface and said proximal end portion of the tube on which it is carried.

6. The apparatus of Claim 5 wherein said electrical conductor comprises a relatively wide and thin strip of conductive material.

7. The apparatus of Claim 5 in which the tube on which said electrode is carried comprises a wall defined by inner and outer layers of non-conductive material, and said conductor is located therebetween.

8. The apparatus of Claim 3 further comprising a pair of electrical conductors carried by said inner tube, each conductor extending between one of said electrode surfaces and the proximal end portion of said inner tube.

9. The apparatus of Claim 8 wherein said conductors are in the form of relatively thin and wide strips carried on the outer surface of said inner tube.

10. The apparatus of Claim 9 wherein the outer tube has a non-conductive inner surface.

11. The apparatus of Claim 1 wherein at least the surface of said inner and outer tubes is comprised of non-conductive material.

12. The apparatus of Claim 4 wherein said outer tube comprises a wall including non-conductive inner and outer surfaces and an electrical conductor therebetween extending between said additional electrode surface and the proximal end portion of said outer tube.

13. The apparatus of Claim 2 further comprising a radio frequency power source having a monopolar active terminal and a return terminal, and said at least one electrode surface is in electrical communication with one of said terminals and the said additional electrode surface is in electrical communication with the other of said terminals.

14. The apparatus of Claim 1 wherein the inner and outer tubes are relatively axially movable.

15. The apparatus of Claim 1 further comprising a hand piece located at the proximal end of said shaft.

16. The apparatus of Claim 15 further comprising a motor disposed within said hand piece and operable to rotate said rotatable tube or tubes, and said apparatus further comprising a power supply disposed in said hand piece and operatively connected to said motor.

17. The apparatus of Claim 16 wherein said elongated shaft is removable from said hand piece.

18. Apparatus for morselating tissue within a body cavity of a patient comprising:

an elongated tube having proximal and distal end portions and defined by a wall;

5 a pair of spaced-apart electrode surfaces carried at the distal end of tube; and

a pair of electrical conductors extending between one of said electrode surfaces and the proximal end of said tube.

19. A method for removing tissue from within a body cavity of a patient through an incision in the patient comprising:

5 inserting through an incision in the patient the distal end of an elongated shaft having proximal and distal end portions, the elongated shaft comprising an outer tube and an inner tube disposed within the outer tube, the inner tube having a lumen extending between the proximal and distal end portions and at least one of said  
10 inner and outer tubes being rotatable;

energizing an electrode carried on the distal end of a rotatable one of said tubes by electrically coupling the electrode to a source of radio frequency energy;

rotating said rotatable tube and the electrode;

15           advancing the energized rotating electrode into the tissue to be removed to morselate the tissue; and  
          removing the morselated tissue through the lumen of the inner tube.

20. The method of Claim 19 wherein the electrode is an active electrode.

21. The method of Claim 20 wherein the elongated shaft includes at least an additional electrode at the distal end portion thereof and wherein the additional electrode is a return electrode.

22. The method of Claim 21 wherein the electrodes are both carried on the distal end of the inner tube.

23. The method of Claim 19 wherein the step of removing includes suctioning the morselated tissue through the lumen of the inner tube.

24. The method of Claim 19 wherein the morselating and removing steps occur simultaneously.

25. The method of Claim 19 further including:  
          inserting a resected tissue container through an incision in the patient and placing the resected tissue into the container before inserting the elongated shaft;  
5           inserting the distal end of the elongated shaft into the container; and  
          carry out the energizing, rotating, advancing and removing steps inside the container.

26. The method of Claim 25 wherein the tissue container has an inside surface that is non-conductive, and wherein the elongated shaft includes an additional electrode at the distal end thereof and wherein one of the

25

- 5        electrode is an active electrode and the other of the electrodes is a return.

27. The method of Claim 25 wherein the inside surface of the container is silicone.

28. The method of Claim 19 wherein the tissue container has an inside surface that is conductive and defines an electrode of opposite polarity to the electrode carried by the shaft.

29. The method of Claim 27 including pressing the distal end of the shaft against the inside surface of the container after advancing it into the tissue to fully sever the morselated tissue.

30. Apparatus for morselating resected tissue within a body cavity of a patient, said apparatus comprising, in combination:

- 5        a tissue container insertable through an incision into a body cavity of a patient, said container defining an interior chamber for containing therein the resected tissue that is to be morselated;

10        a morselator having a proximal end portion, a distal end portion and an electrode of selected polarity carried on the distal end portion and operable to assist in morselating resected tissue, said distal end portion being insertable through an incision into the body cavity and into said tissue container for morselating the resected tissue there within; and

- 15        a second electrode disposed within the tissue container of opposite polarity to the first-mentioned electrode.

31. The apparatus of Claim 30 wherein said tissue container includes an interior surface comprised of a

substantially conductive material and defines the second electrode.

32. The apparatus of Claim 31 wherein said tissue container comprises an exterior surface of substantially non-conductive material.

5 33. The apparatus of Claim 30 wherein said morselator further comprises an elongated shaft having proximal and distal end portions and at the first mentioned and the second electrodes are carried on said distal end portion, one or both of said electrodes being rotatable to morselate resected tissue, and wherein said tissue container is defined by a wall comprising at least an inner surface of non-conductive material.

34. The apparatus of Claim 33 wherein said elongated shaft comprises inner and outer coaxial tubes, said inner tube being rotatable and both of said electrodes being carried on said inner tube.

5 35. The apparatus of Claim 33 wherein said elongated shaft comprises inner and outer coaxial tubes, said tubes being relatively rotatable and one of said electrodes being carried on the inner tube and the second electrode is carried on the outer tube.

5 36. A containment vessel for receiving resected tissue comprising: a flexible wall defining an inner chamber adapted to be received within a body cavity of a patient, said wall comprising a non-conductive outer surface and a conductive inner surface.

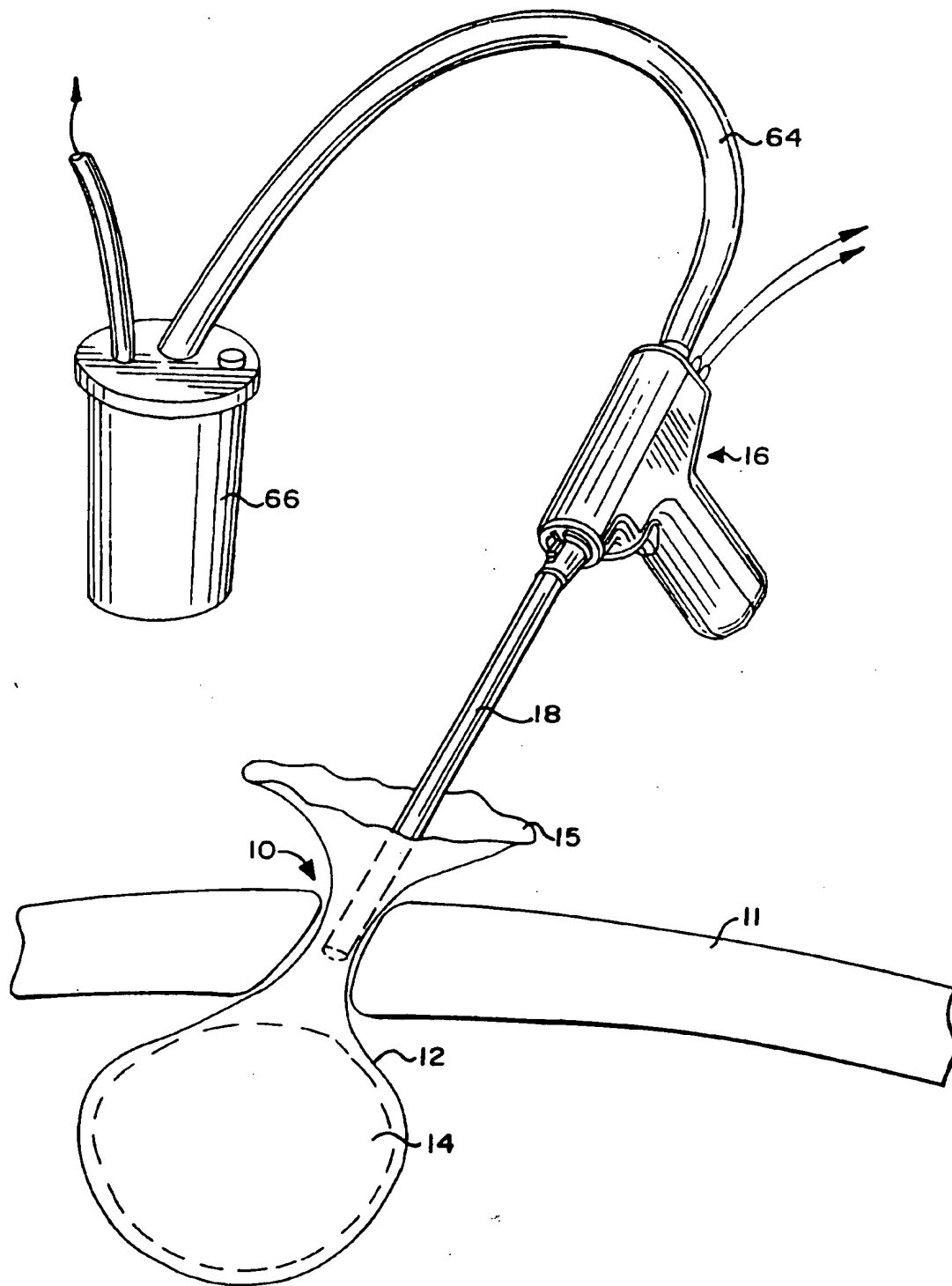
37. The containment vessel of Claim 36 wherein said non-conductive outer surface comprises silicone.

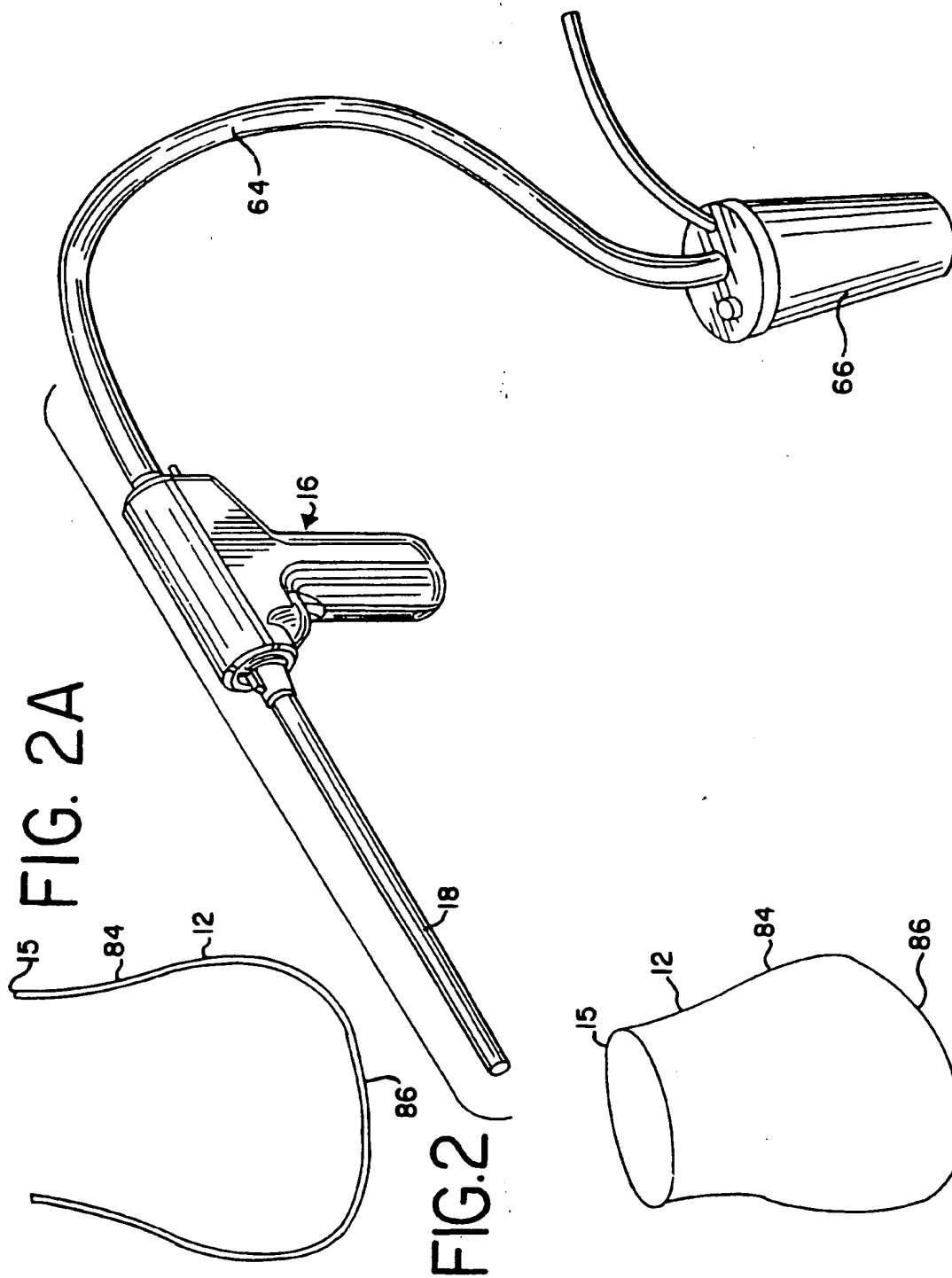
38. The containment vessel of Claim 36 wherein said containment vessel is a bag or pouch.

39. The apparatus of Claim 18 further comprising a drive unit carried at the proximal end of said tube and including a motor selectively operable to rotate said tube and a pair of connectors in electrical communication with said conductors for connection to a radio frequency power supply.

40. The apparatus of Claim 18 wherein said wall comprises non-conductive inner and outer surfaces, and said pair of electrical conductors are located between said non-conductive surfaces.

FIG. 1





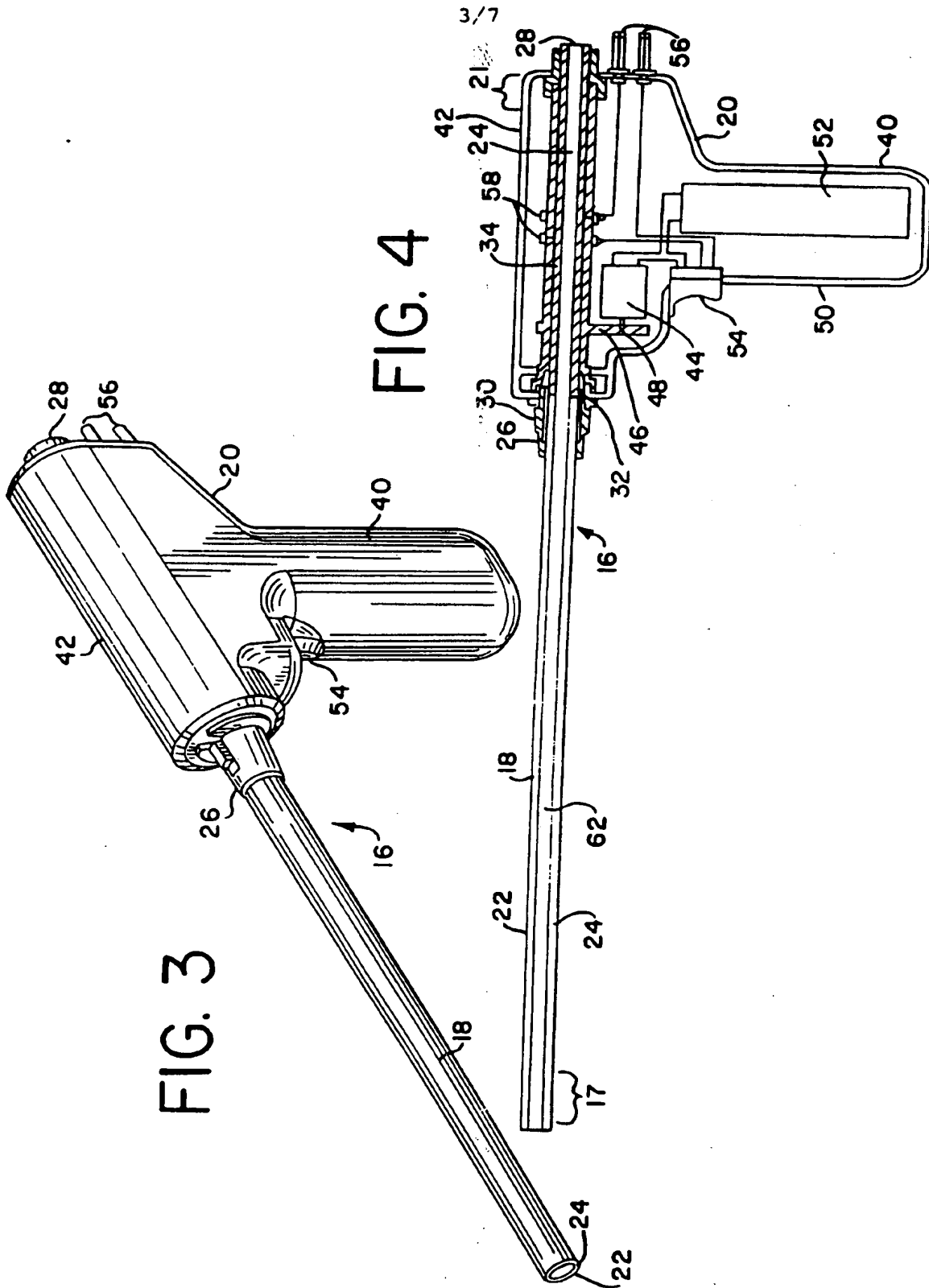


FIG. 5

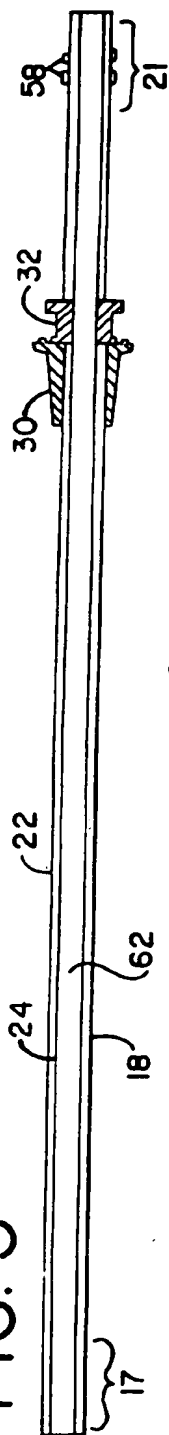


FIG. 5b

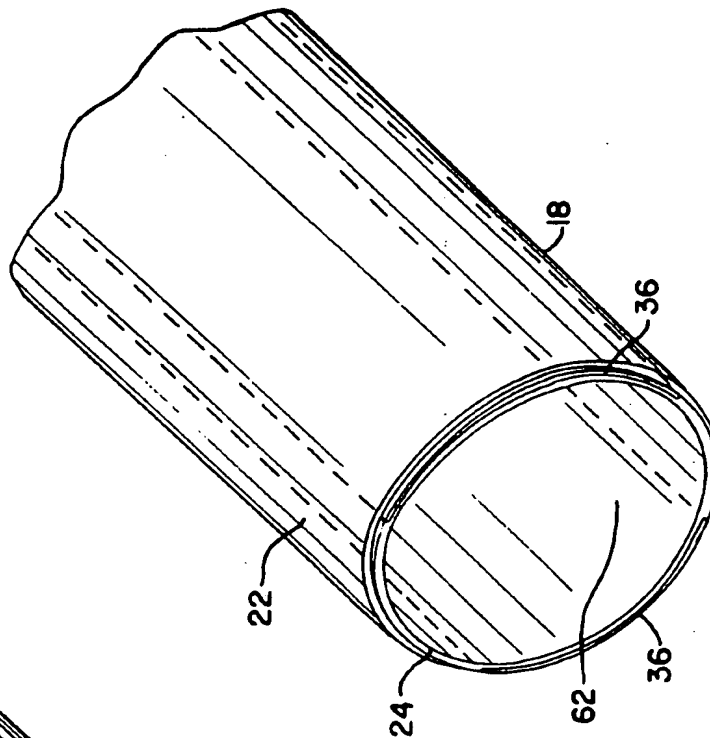


FIG. 5a

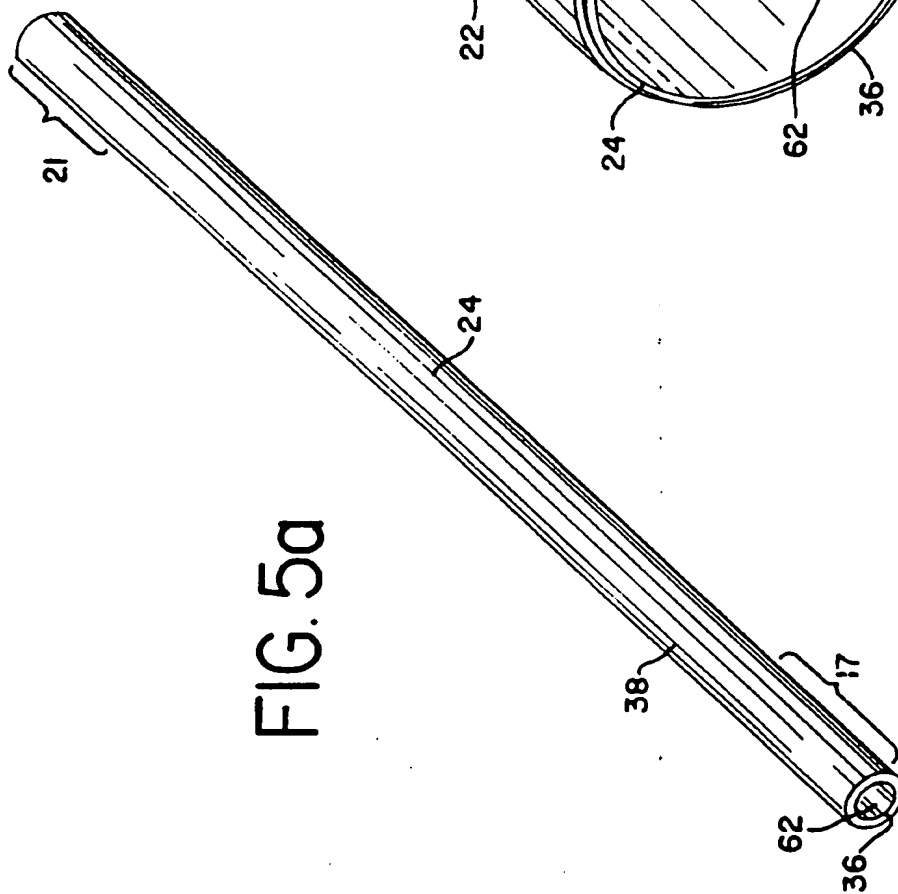


FIG. 6a

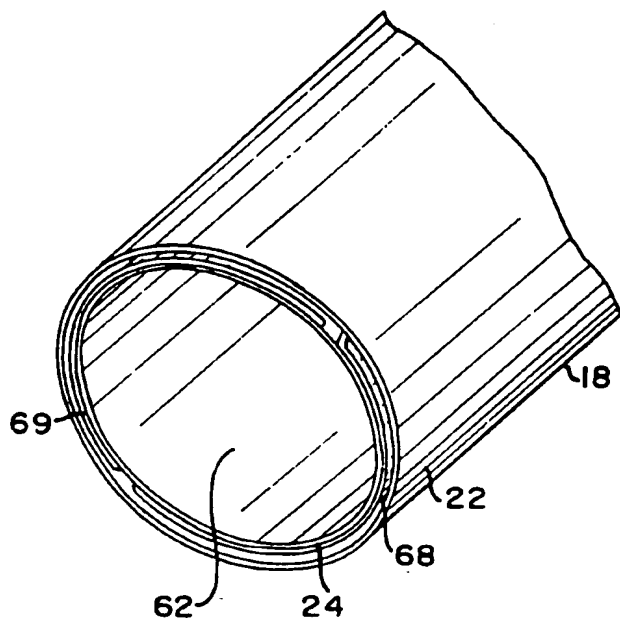


FIG. 6b

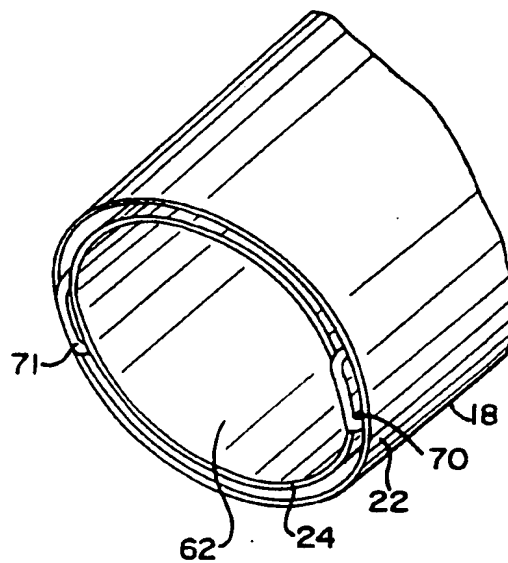


FIG. 6c

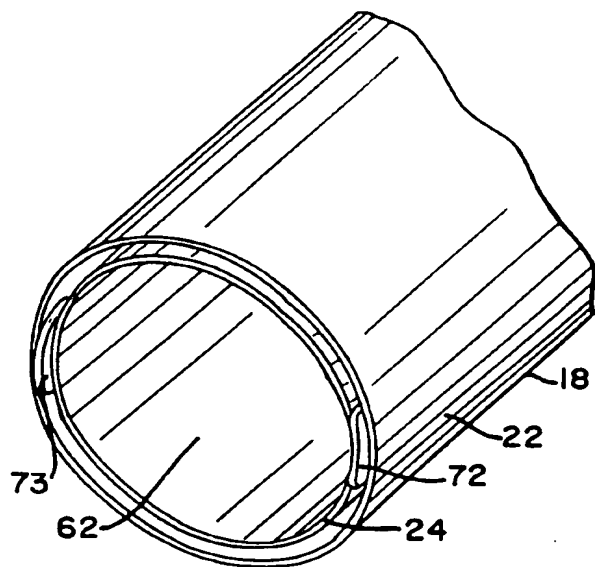


FIG. 6d

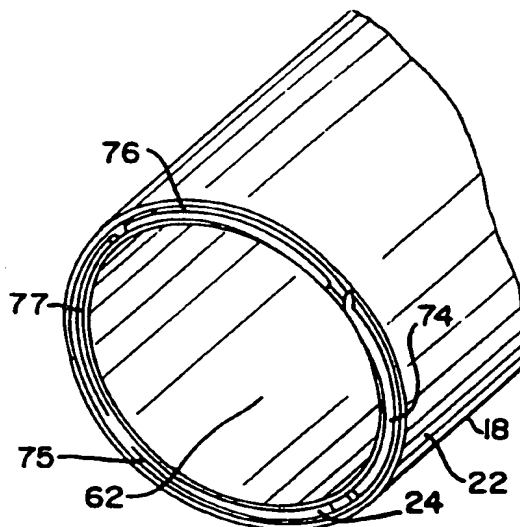


FIG. 6e

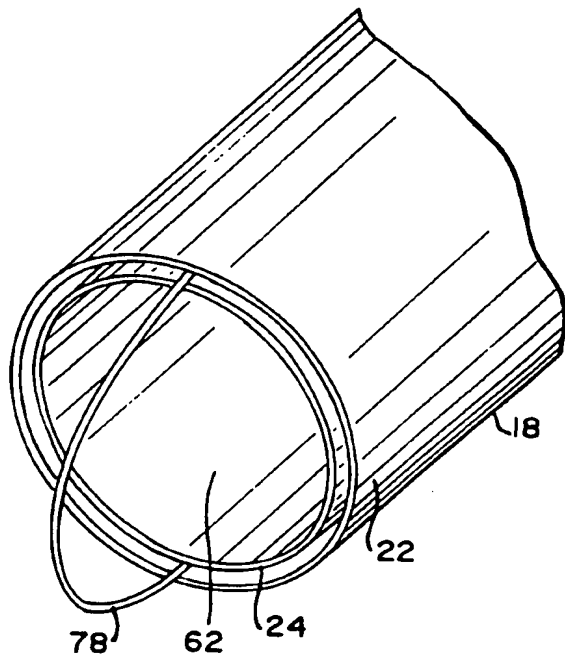


FIG. 6f

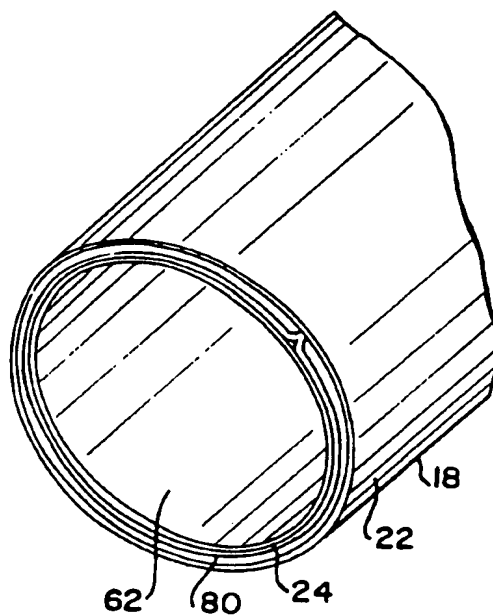
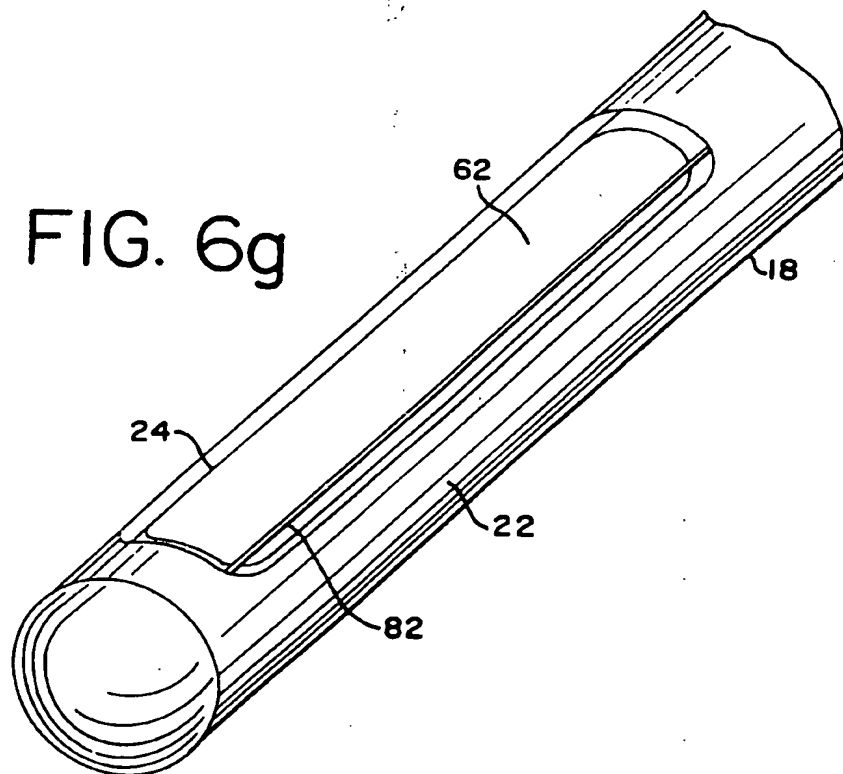
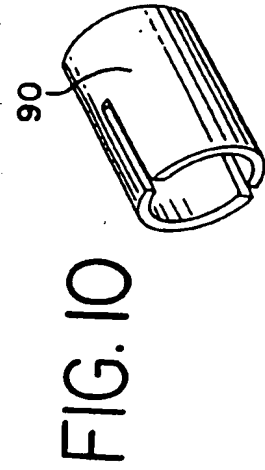
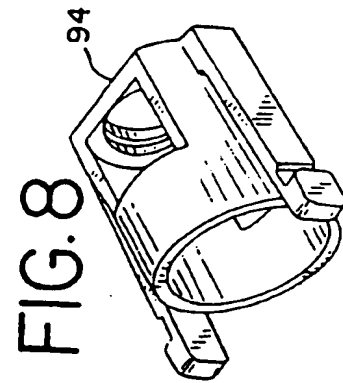
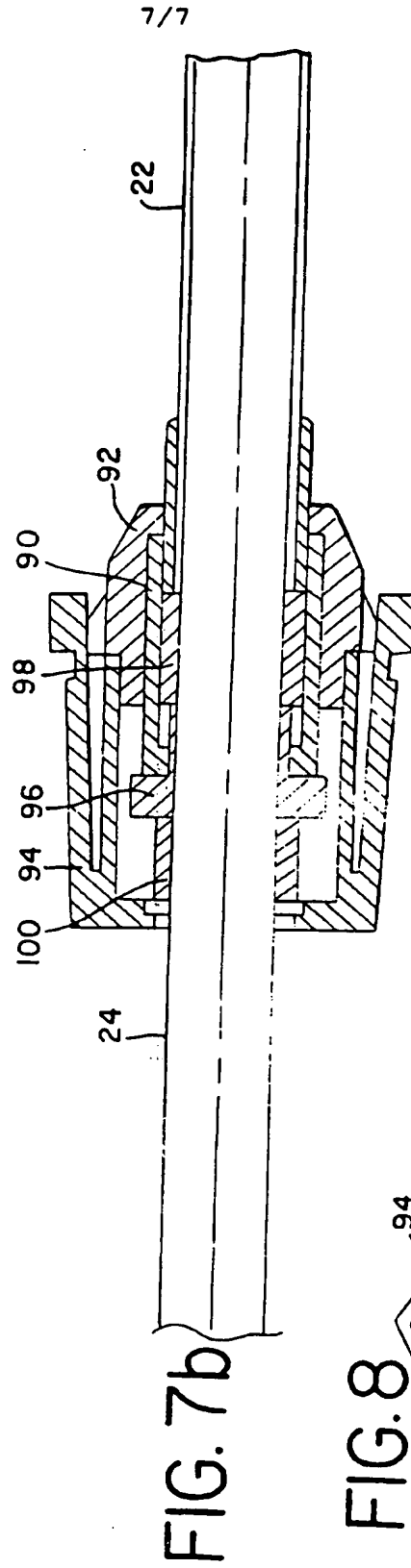
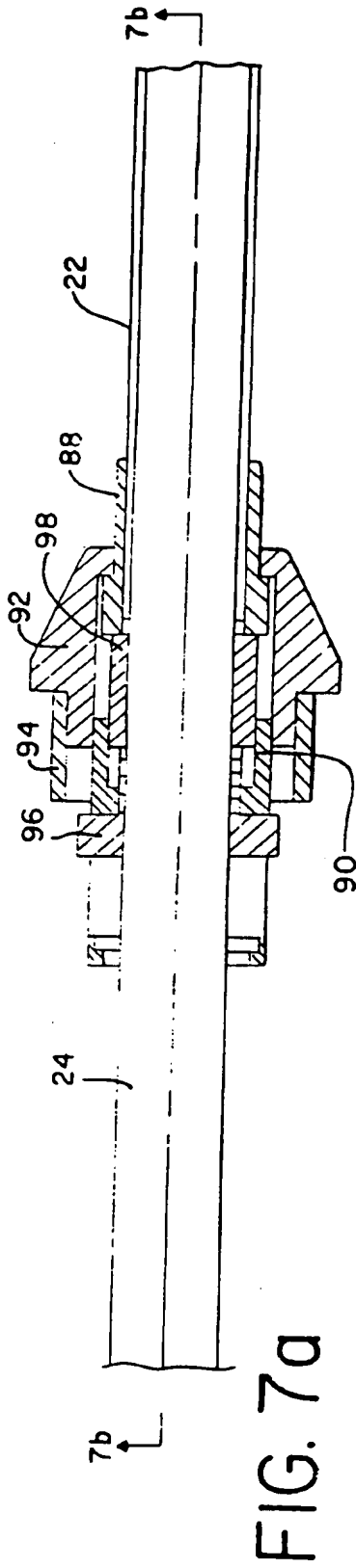


FIG. 6g





## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/01547

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/20, 17/36; A61M 5/32

US CL : 604/ 22, 163; 606/39

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : Please See Extra Sheet.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,016,881 (RIOUX ET AL.) 12 April 1977, column 3 lines 48-68, and column 4 lines 1-9.	18, 40
X	US, A, 5,037,379 (CLAYMAN ET AL.) 06 August 1991, see column 5 lines 20-36.	36-38
---		-----
Y		19-35
Y	US, A, 5,320,627 (SORENSEN ET AL.) 14 June 1994, column 8 lines 1-68, and column 9 lines 1-48.	1-17, 39
A	US, A, 3,945,375 (BANKO) 23 March 1976, column 2 lines 34-66, and column 2 lines 13-59.	1-18, 39, 40

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

Special categories of cited documents:	
*A* document defining the general state of the art which is not considered to be part of particular relevance	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*E* earlier document published on or after the international filing date	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*O* document referring to an oral disclosure, use, exhibition or other means	*Z* document member of the same patent family
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

11 APRIL 1996

Date of mailing of the international search report

09 MAY 1996

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Authorized officer

LARRY KNIGHTS

Facsimile No. (703) 305-3230

Telephone No. (703) 308-3175

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/01547

## B. FIELDS SEARCHED

Minimum documentation searched

Classification System: U.S.

128/ 898; 604/ 22, 28, 43, 44, 117, 158-163, 171, 173, 285, 317, 322, 326, 327, 408; 606/ 1, 32, 37, 39, 40, 45,  
151, 167, 170, 171, 180